K021778

9.0 510(k) Summary

JUL 17 2002

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
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Philips Medical Systems
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This summary was prepared on 29 May, 2002

2. The name of this device is the Philips Medical Systems, M1275B Component Compact Monitor. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Anesthesiology and Respiratory Therapy Devices Panel (12624)	868.1400, II	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
	868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	868.1700, II	CBR	Analyzer, Gas, Nitrous-Oxide, Gaseous Phase (Anesthetic Concentration)
	868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	868.2375, II	BZQ	Monitor, Breathing Frequency
	868.2480, II	LKD	Monitor, Carbon-Dioxide, Cutaneous
	868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
Circulatory System Devices Panel (12625)	870.1025, III	DSI	Detector and Alarm, Arrhythmia
	870.1025, III	MLD	Monitor, ST Segment with Alarm
	870.1025, III	MHX	Monitor, Physiological, Patient (with arrhythmia Detection or alarms)
	870.1100, II	DSJ	Alarm, Blood-Pressure
	870.1110, II	DSK	Computer, Blood-Pressure

Device Panel	Classification	ProCode	Description
	870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	870.1915, II	KRB	Probe, Thermodilution
	870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	870.2340, II	DPS	Electrocardiograph
	870.2340, II	MLC	Monitor, ST Segment
	870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	870.2450, II	DXJ	Display, Cathode-Ray Tube, Medical
	870.2600, I	DRJ	System, Signal Isolation
	870.2700, II	DQA	Oximeter
	870.2770, II	DSB	Plethysmograph, Impedance
	870.2800, II	DSH	Recorder, Magnetic Tape, Medical
	870.2810, I	DSF	Recorder, Paper Chart
	-	MSX	System,Network and Communication, Physiological Monitors
General Hospital and Personal Use Devices Panel (12520)	880.2910, II	FLL	Thermometer, electronic, clinical
Neurological Devices Panel (12513)	882.1400, II	GWR	Electroencephalograph
	882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The new device is substantially equivalent to the previously cleared Philips Component Compact Monitor (M1275B) device marketed pursuant to K013199, K020531, and K021300, the Philips Component Monitoring System marketed pursuant to K990125 with the Philips M1021A SvO_2 Module marketed pursuant to K942843, the Philips M1027A EEG Module marketed pursuant to K992674, the Philips M1034A BIS Module marketed pursuant to K003038, and the Philips M2391A PC Client marketed pursuant to K021422.

4. The modification is updated software and the ability to support to the Philips M1021A SvO_2 Module, M1027A EEG Module, and M1034A BIS Module as well as the M2385A Application Server.

5. The new device has the same Indications for Use, for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients, as the legally marketed predicate device.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that Component Compact Monitor meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Mr. Dave Osborn
Philips Medical Systems
3000 Minuteman Road
Andover, Massachusetts 01810

Re: K021778
Philips Component Compact Monitor, Release A.04, M1275B
Regulation Number: 870.2700, 882.1400, 870.1025
Regulation Name: Oximeter, Electroencephalograph, and Arrhythmia Detector and Alarm
Regulatory Class: III
Product Code: DQA, GWQ, and MHX
Dated: May 29, 2002
Received: May 30, 2002

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021778

Device Name: Philips Medical Systems, M1275B Component Compact Monitor, Release A.04, with M1021A SvO_2 Module, M1027A EEG Module, and M1034A BIS Module.

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters patients.

Intended use: For monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities.

EASI 12-lead ECG is only for use on adult and pediatric patients.

ST Segment monitoring is restricted to adult patients only.

The transcutaneous gas measurement ($tcpO_2$ / $tcpCO_2$) is restricted to neonatal patients only.

Bispectral Index (BIS) monitoring is for use in monitoring the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room, and for clinical research. The Bispectral Index, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents*.

* Gan TJ, Slass P, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index Monitoring Allows Faster emergence and Improved Recovery from Propofol, Alfentanil, and Nitrous Oxide Anesthesia. Anesthesiology October 1997; (4) 87:808-15.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021778